

MENS ROGAINE EXTRA STRENGTH- minoxidil solution
Johnson & Johnson Healthcare Products, Division of McNEIL-PPC, Inc.

Men's Rogaine Extra Strength 5%
Unscented Solution
Carton

Drug Facts

Active ingredient

Minoxidil 5% w/v

Purpose

Hair regrowth treatment for men

Use

to regrow hair on the top of the scalp (vertex only, see pictures on side of carton)

Warnings

For external use only. For use by men only.

Flammable: Keep away from fire or flame

Do not use if

- you are a woman
- your amount of hair loss is different than that shown on the side of this carton or your hair loss is on the front of the scalp. 5% minoxidil topical solution is not intended for frontal baldness or receding hairline.
- you have no family history of hair loss
- your hair loss is sudden and/or patchy
- you do not know the reason for your hair loss
- you are under 18 years of age. Do not use on babies and children.
- your scalp is red, inflamed, infected, irritated, or painful
- you use other medicines on the scalp

Ask a doctor before use if you have heart disease

When using this product

- do not apply on other parts of the body
- avoid contact with the eyes. In case of accidental contact, rinse eyes with large amounts of cool tap water.
- some people have experienced changes in hair color and/or texture
- it takes time to regrow hair. Results may occur at 2 months with twice a day usage. For some men, you may need to use this product for at least 4 months before you see results.
- the amount of hair regrowth is different for each person. This product will not work for all men.

Stop use and ask a doctor if

- chest pain, rapid heartbeat, faintness, or dizziness occurs

- sudden, unexplained weight gain occurs
- your hands or feet swell
- scalp irritation or redness occurs
- unwanted facial hair growth occurs
- you do not see hair regrowth in 4 months

May be harmful if used when pregnant or breast-feeding.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply one mL with dropper 2 times a day directly onto the scalp in the hair loss area
- using more or more often will not improve results
- continued use is necessary to increase and keep your hair regrowth, or hair loss will begin again

Other information

- see hair loss pictures on side of this carton
- before use, read all information on carton and enclosed booklet
- keep the carton. It contains important information.
- hair regrowth has not been shown to last longer than 48 weeks in large clinical trials with continuous treatment with 5% minoxidil topical solution for men
- in clinical studies with mostly white men aged 18-49 years with moderate degrees of hair loss, 5% minoxidil topical solution for men provided more hair regrowth than 2% minoxidil topical solution
- store at controlled room temperature 20° to 25° C (68° to 77° F)

Inactive ingredients

alcohol, propylene glycol, purified water

Questions?

- call us at **1-800-ROGAINE** (1-800-764-2463)
- visit **rogaine.com**

PRINCIPAL DISPLAY PANEL - 60 mL Bottle Carton

MEN'S

Rogaine®

EXTRA STRENGTH

5% MINOXIDIL

TOPICAL SOLUTION

HAIR REGROWTH

TREATMENT

UNSCENTED

CLINICALLY PROVEN

TO HELP REGROW HAIR

REACTIVATES HAIR FOLLICLES

TO STIMULATE REGROWTH

#1 Dermatologist Recommended Brand

Not For Use By Women

One Month Supply

1–60 mL (2 fl oz) Bottle

APPROVED

FDA

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Rogaine
EXTRA STRENGTH

5% MINOXIDIL TOPICAL SOLUTION
HAIR REGROWTH TREATMENT
UNSCENTED

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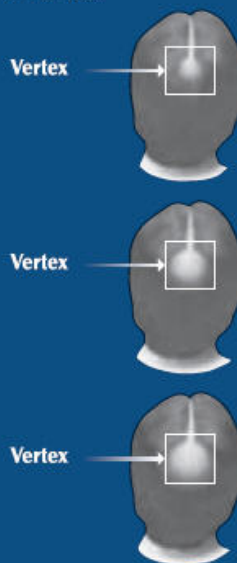


MEN'S
Rogaine
EXTRA STRENGTH

5% MINOXIDIL TOPICAL SOLUTION
HAIR REGROWTH
TREATMENT

Men's Rogaine® Extra Strength is for men who have a general thinning of hair on the top of the scalp (vertex only, as shown below). Not intended for frontal baldness or a receding hairline.

Men's Rogaine® Extra Strength has been shown to regrow hair in men with the following degrees of thinning hair or hair loss.



If men have more hair loss or hair loss in a place different than shown above, *Men's Rogaine® Extra Strength* may not work.



LOT/EXP

Drug Facts

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Minoxidil 5% w/v.....Hair regrowth treatment for men

Purpose

Use to regrow hair on the top of the scalp (vertex only, see pictures on side of carton)

Warnings

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- you have no family history of hair loss
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- you do not know the reason for your hair loss
- you are under 18 years of age. Do not use on babies and children.
- your scalp is red, inflamed, infected, irritated, or painful
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- the amount of hair regrowth is different for each person. This product will not work for all men.

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- chest pain, rapid heartbeat, faintness, or dizziness occurs
- sudden, unexplained weight gain occurs
- your hands or feet swell
- scalp irritation or redness occurs
- unwanted facial hair growth occurs
- you do not see hair regrowth in 4 months

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MEN'S
Rogaine[®]
EXTRA STRENGTH

5% MINOXIDIL TOPICAL SOLUTION HAIR REGROWTH TREATMENT

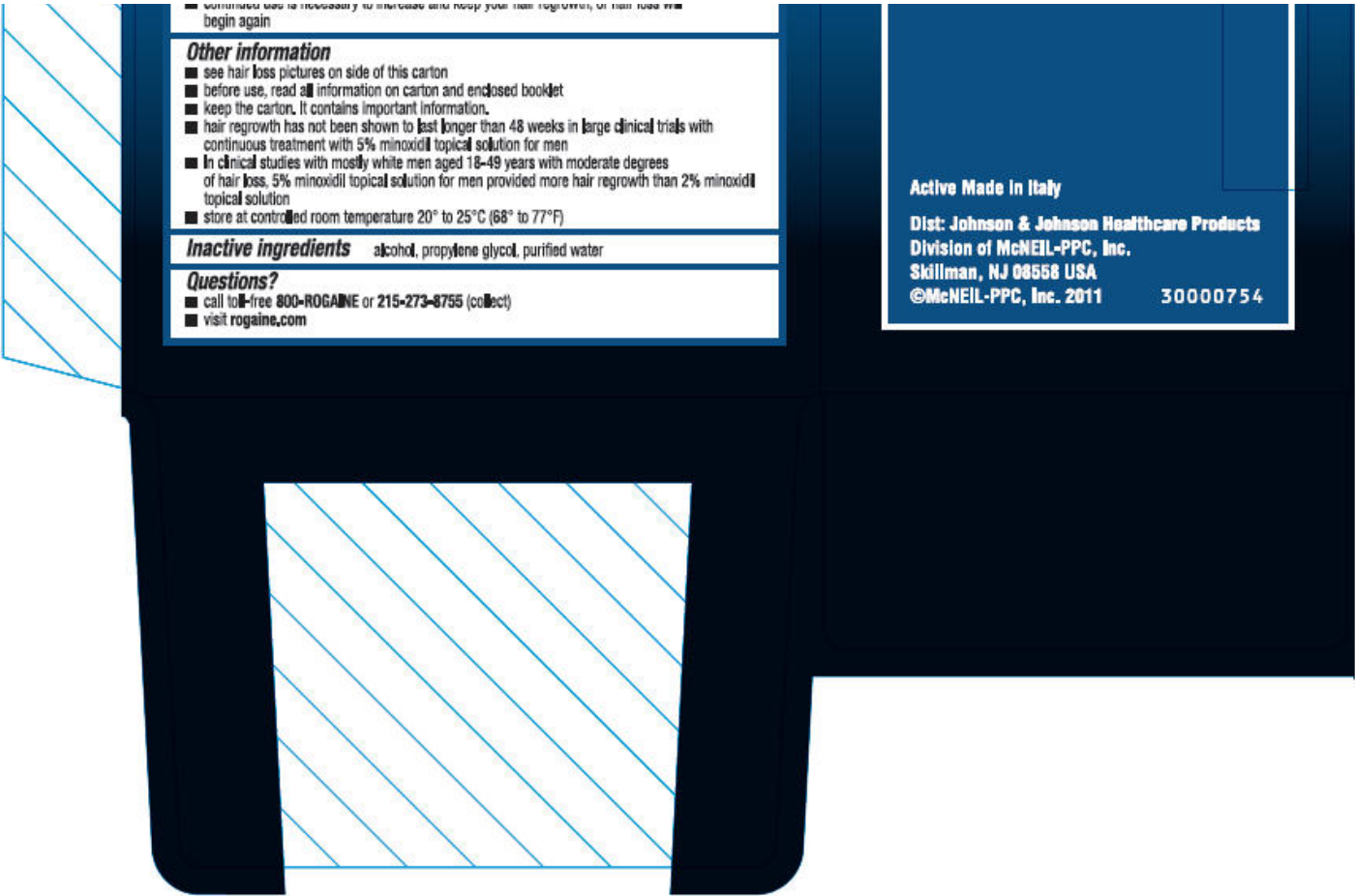
THIS PACKAGE CONTAINS:

- One 60 mL (2 fl oz) Bottle of **Men's Rogaine[®] Extra Strength** (one month supply)
- One child-resistant dropper applicator
- Information booklet with complete directions on how to use and obtain best results



FOR BEST RESULTS

APPLY DIRECTLY TO SCALP
TWICE DAILY



MENS ROGAINE EXTRA STRENGTH				
minoxidil solution				
Product Information				
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:42002-101	
Route of Administration	TOPICAL	DEA Schedule		
Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength		Strength	
Minoxidil (Minoxidil)	Minoxidil		50 mg in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
Alcohol				
Propylene Glycol				
Water				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:42002-101-02	1 in 1 CARTON		
1		60 mL in 1 BOTTLE, PLASTIC		
2	NDC:42002-101-06	3 in 1 CARTON		
2		60 mL in 1 BOTTLE, PLASTIC		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA		NDA020834	07/16/2010	

Labeler - Johnson & Johnson Healthcare Products, Division of McNEIL-PPC, Inc. (831417154)

Revised: 3/2012 Johnson & Johnson Healthcare Products, Division of McNEIL-PPC, Inc.